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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,658

08/16/2006

Kazuhiko Katou

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05/27/2010

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

WELTER, RACHAEL E

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

05/27/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/589,658	Applicant(s) KATOU ET AL.	
	Examiner RACHAEL E. WELTER	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/29/10.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/16/06, 11/13/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of three binders: sodium carboxymethylcellulose, xanthan gum, and carrageenan in the reply filed 4/29/10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus, the election of species requirement is deemed proper and is made FINAL noting applicant's right to pursue the non-elected groups or species in one or more divisional applications.

Claim Status

Claims 1-6 are pending.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on August 16, 2006 and November 13, 2006 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. Accordingly, the information disclosure statements were considered by the examiner. A signed copy of forms 1449 are enclosed herewith.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is

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requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leusch et al (WO 00/56276) in view of De Sadeleer et al (US Patent No. 5,973,212).

Leusch et al teach oral care compositions including tooth pastes, mouth rinses, mouth sprays, chewing gums, and lozenges (abstract). In Example VI of Leusch et al, a composition comprising 10 wt.% erythritol, 0.31 wt.% xanthan gum, 0.45 wt.% carboxymethyl cellulose, and 23.56 wt.% water is taught (pg. 19). Leusch et al further teach that erythritol and other non-cariogenic carbohydrates can be comprised in the composition in an amount of 1-65 wt.% (pg. 3, lines 1-2). Besides sodium

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carboxymethyl cellulose and xanthan gum, Leusch et al teach additional thickening agents such as carrageenan (pg. 9, lines 1-6). Such thickening agents can be present in an amount of 0.1-15 wt.% and preferably 2-10 wt.% (pg. 9, lines 18-20). Additionally, Leusch et al teach that coolants can be added to its compositions (pg. 10, lines 5-8).

Although the particle size of erythritol in Leusch et al may be the same as claimed, Leusch et al do not explicitly teach erythritol having an average particle size of 200 um or less.

De Sadeleer et al teach erythritol compositions which are useful in tabletting, chewing gum, chocolate, crystallized tablets, and fondants (column 2, lines 1-2). The erythritol preferably has a particle size of 10-250 microns (column 2, lines 17-19). According to De Sadeleer et al, the perception of cooling effect by the mouth is dependent upon the particle size of the erythritol crystals and for maximum effect it is desirable to use small but integral and non-fragmented crystals in its applications (column 2, lines 56-63).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to incorporate the instant particle size of erythritol in the compositions of Leusch et al. One would have been motivated with a reasonable expectation of success since De Sadeleer et al teach that such particle sizes are preferable in creating a cooling effect and Leusch desires the optional use of coolants in its compositions. Thus, if one desired to provide an oral care composition with a cooling effect, one would be motivated to add erythritol with the instant particle size.

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Regarding the instant limitation of claim 6, wherein the composition has a viscosity at 25°C from 1500-5000 dPas, it is the position of the examiner that this would be an obvious expected property of the composition taught by Leusch et al and De Sadeleer et al because the prior art suggests the same components as the instant application including the erythritol, water, and binders. According to MPEP 2112.02, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). Furthermore, as evidenced by the instant specification, a binder content exceeding 3 wt.% has an unduly high viscosity (see paragraph 0014). Since Leusch et al suggest the instant binder amount; it is assumed that the composition of Leusch et al exhibits the instant viscosity.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based

on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of copending Application No. 11/512326. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending claims are drawn to a dentrifice composition comprising 15-60 wt.% erythritol having a particle size of less than 355 um, 10-40 wt.% water, and 0.6-3 wt.% binder. The binders can be selected from sodium carboxymethylcellulose, xanthan gum, and carrageenan.

Although the copending claims do not teach the same amounts of erythritol and water as the instant claims, the copending claims recite amounts that overlap with the instant claims.

However, it would have been obvious to an artisan ordinary skill at the time the invention was made manipulate and optimize the amount of water and erythritol in the composition of the copending claims. One would have been motivated to determine the optimal amount of each ingredient in order to best achieve the desired results. It should be noted that generally difference in concentrations do not support the patentability of

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subject matter encompassed by the prior art unless there is evidence indicating such a concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding the instant limitation of claim 6, wherein the composition has a viscosity at 25°C from 1500-5000 dPas, it is the position of the examiner that this would be an obvious expected property of the composition recited by the copending claims because the claims recite the same components as the instant application including erythritol, water, and binders. According to MPEP 2112.02, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). Furthermore, as evidenced by the instant specification, a binder content exceeding 3 wt.% has an unduly high viscosity (see paragraph 0014). Since the copending claims recite the same binder amount as the instant claims, it is assumed that the composition of the copending claims exhibits the instant viscosity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

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Claims 1-6 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
May 21, 2010